19. (currently amended) A method of thickening a composition comprising biliquid foam dispersed in a salt-containing aqueous phase having a pH less than ~~about~~ 7 comprising gelling the aqueous phase with a polymeric sulfonic acid gellant; the salt contained in the aqueous phase being present in the composition in an amount in the range of from about 1 to about 10 percent, the gellant being present in the composition in an amount in the range of from about 0.01 to about 10 percent, and the composition comprising less than about 1 percent surfactant, wherein said weights are by weight of the total composition.

20. (original) The method of claim 19 in which the gellant is ammonium poly(acryldimethyltauramide-co-vinylformamide).

21. (original) The composition of claim 20 in which the gellant is present in an amount of from about 1 to about 10% by weight of the total composition.

REMARKS

35 USC §103(a)

Claims 1-21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wheeler (WO 97/32559) in view of the Clariant product brochure. The rejection states in relevant part:

> The amended claim recites a pH of less than about 7 and this pH is less than 7; also, Wheeler teaches pH of 6.5 in example 3 and this pH is less than 7. Wheeler teaches Carbomer as a gellant but the secondary reference, Clariant product brochure, teaches polymer sulfonic acid as gelling agent for systems such as the one disclosed by Wheeler and one gelling agent can be substituted for another and expect the gelling of the aqueous solution to take place. The declaration is not commensurate with the scope of the claims. Since the secondary reference teaches polymeric acid as a gellant, and since one gellant can be substituted for another, prediction or lack of prediction of the superiority of the polymeric sulfonic acid over the carbomer would not distinguish over the composition formed by substituting polymer sulfonic acid for carbomer since the same effect is obtained.
>
> The instant claims do not exclude surfactants from the composition. The composition comprising large amounts of surfactants also contains gelling agents. Although, applicants contend that in the case when the composition has large amounts of surfactants, the pH is adjusted to 7, it is respectfully submitted

> that less than about pH 7 is not different than pH 7 and the secondary reference is relied upon for a gelling agent and one gelling agent can be used in place of another; applicants have not shown that large amounts of surfactants interferes with either the polymeric sulfonic acid gelling agent or prevents the gelling process.

The rejection is respectfully traversed. Prior to addressing the merits of the rejection, the Applicants wish to restate the nature of the present invention. The instant invention provides an improved aqueous gel formulation that can be used to deliver the necessary therapeutic agents while retaining the stability and the elegant texture of a gel product. The composition comprises an oil-containing biliquid foam dispersed in a salt-containing aqueous phase, the aqueous phase having a pH of less than 7 and comprising a polymeric sulfonic acid gellant. The otherwise unstable biliquid foam is stabilized in the presence of the aqueous gel containing the polymeric sulfonic acid gellant and very little surfactant. Unlike known compositions of similar utility, the claimed invention utilizes a polymeric sulfonic acid gelling agent which can be used in the presence of substantial amounts of electrolytes in an aqueous phase having a pH of less than 7 without harmful effects on the texture of the gel.

To further distinguish the invention over the cited art, claims 1, 12 and 19 have been amended to recite a pH of the aqueous phase of less than 7, based on the disclosure in the present specification at page 2, line 6, page 3, line 13, and page 4, line 8. The independent claims as amended also further specify the amounts of the components in the claimed composition. The amended claims recite a range of the salt in an amount in the range of from about 1 to about 10 percent (page 3, lines 6 and 7 of the present specification), an amount of the gellant of from about 0.01 to about 10 percent (page 3, lines 4 and 5 of the present specification), and less than about 1 percent surfactant in the total composition (page 5, lines 21 and 22, and claims 11 and 17 of the present specification).

It is the Examiner's position that Wheeler discloses the Applicant's invention except for the polymeric sulfonic acid gellant, but that the Clariant brochure teaches the use of a polymeric sulfonic acid gellant in low pH formulations of the type disclosed in Wheeler, such that it would have been obvious to a person skilled in the art to substitute

the gellant in Clariant for the gellants disclosed in Wheeler to arrive at the Applicants' invention.

Turning first to Wheeler, the Applicants acknowledge that the reference discloses compositions containing a biliquid foam, the foam containing very small amounts of surfactant (see example 1 in which the biliquid foam contains a total of 0.95% surfactants – polyoxyethylene lauryl ether and lauryl betaine). Nevertheless, in addition to the lack of any disclosure or suggestion in the reference to use a polymeric sulfonic acid gellant, the reference also fails to disclose a formulation in which the aqueous phase has a pH of less than 7, wherein the total formulation comprises less than 1% by weight of surfactant. Examples 2 and 3 of the reference are the sole formulations disclosed as having a pH less than 7. However, these formulations each contain over 20 weight percent surfactants. The surfactants, in addition to the surfactants in the biliquid foam, include ammonium lauryl sulphate, ammonium lauryl ether sulphate, cocamidopropyl betaine, coconut diethanolamide and cetostearyl alcohol. The amount of the aqueous ammonium lauryl sulphate alone in each of the example 2 and 3 formulations is 13.5% (.33 x 41). As disclosed in the reference at page 5, line 27 – page 6, line 10, shampoos and shower gels generally contain 4-18% by weight of a primary surfactant and 2-15% by weight of a coactive surfactant. It is disclosed in particular on page 5, lines 7-10 that "It is clear from the above description that by the nature of the conventional formulations this kind of dispersion contains a higher proportion of surfactant than those previously described as features of the invention." In fact, it is well known that, particularly in shampoos, surfactants are the primary cleansing agent and that surfactants are selected based on proper detergency without degreasing (cleaning without removing too much oil from the hair), ability to form delicate and rich bubbling, easy rinsing, good finish after washing hair, minimal skin/eye irritation, no damage to hair, low toxicity and good biodegradability. Generally, the higher alcohol type-anion surfactant provides the proper detergency and forms rich bubbles, and a non-ionic surfactant is added as coadjuvant. Additionally, the proper balance of surfactants provides a shampoo with a slightly acidic pH of about 5.5 - 6.5, since a basic environment weakens the hair by breaking the disulfide bonds in hair keratin. Citric acid is typically used to provide the desired pH. The cuticle of the hair, which is exposed after the sebum is stripped away, is covered with overlapping scales that are smoothed and soothed in a properly acidic environment. Aggravated scales don't overlap nicely, and

they make hair look dull and feel rough. They can also snag other raised scales on neighboring shafts, resulting in snarls. Therefore, one skilled in the art would not have been motivated by the disclosure in Wheeler to use less than 1% surfactant in a biliquid-containing formulation having an aqueous phase of pH less than 7.

The disclosure in the Clariant brochure does not provide any teaching to compensate for the defects of the disclosure of Wheeler as it relates to the presently claimed formulations. The Clariant brochure merely discloses that the polymeric sulfonic acids of the present invention are known in the art for use as a gellant of an aqueous phase of an emulsion. Therefore, even though it also is disclosed that the gellant may be used under low pH conditions, there is absolutely no disclosure or suggestion to use the polymeric sulfonic acids in formulations of the type disclosed in Wheeler, i.e., dispersions containing a biliquid foam and aqueous gel. As explicitly disclosed in Wheeler (page 3, lines 1-8), the formulations described therein are not emulsions, and are insufficiently stable to form usable cosmetic or pharmaceutical products. Therefore, the Examiner's reasoning that the "Clariant product brochure teaches polymer sulfonic acid as gelling agent for systems such as the one disclosed by Wheeler and one gelling agent can be substituted for another and expect the gelling of the aqueous solution to take place" is entirely unsupportable, and therefore, the combination of the Clariant brochure with the disclosure in Wheeler is improper. Given, however, for the sake of argument, that the combination is a proper one, the combination (substituting the polymeric sulfonic acid gellant of Clariant for the conventional gellants disclosed in Wheeler) would still not result in the Applicants' claimed compositions, since the amount of surfactants in the resulting low pH compositions would far exceed 1%.

For the above reasons alone, the rejection of the claims under 35 USC §103(a) cannot stand. However, the Applicants further submit that the unexpected superiority of the polymeric sulfonic acid in gelling the aqueous dispersions containing biliquid foam in comparison with the carbomer or other gellants disclosed in Wheeler is neither taught nor suggested by either Wheeler or Clariant. As noted in the present specification at page 3, line 26 – page 4, line 6, the gellants recommended for use in Wheeler perform adequately in non-acidic formulations; however, these gellants are incapable of creating a stable dispersions when the aqueous phase to be gelled contains even low levels of electrolytes or salts of desired active ingredients at an acidic pH. The Applicants have

previously submitted two declarations which demonstrate that at pH of less than 7, carbomers, as well as other gellants recommended by Wheeler, do not provide a homogeneous and stable product. As discussed above, the Wheeler formulations wherein the pH is adjusted to less than 7 (examples 2 and 3) contain an enormous quantity of surfactants (greater than 20%) which will counteract any tendency to instability in the use of carbomer as the gellant. In contrast to examples 2 and 3, it is demonstrated in example 4 in Wheeler that, in the absence of large amounts of surfactant, the pH is adjusted to 7. Clearly, the stability of the dispersion containing biliquid foam having a pH of less than 7, in the absence of large quantities of surfactants could not have been predicted from the cited references.

The declarations of Matathia and Harrison unequivocally demonstrate the superiority of the polymeric sulfonic acid in stably gelling the biliquid foam dispersion at pH less than 7. In the Matathia declaration, various gellants were tested in developing the formulations of the present invention, including the carbomer, but only the polymeric sulfonic acid gellant produced an aesthetically and commercially acceptable product. The Harrison declaration compared two formulations (derived from Wheeler example 5, which does not include surfactants in addition to the surfactants used in the biliquid foam). The formulations were adjusted to acidic pH and differed only in the type of gellant used. The results demonstrate that only the formulation using the polymeric sulfonic acid gellant retained its integrity. The traditional gellant recommended in Wheeler did not, in the absence of additional surfactants, produce a stable composition at a pH below 7. It is therefore submitted that the declarations are commensurate with the scope of the amended claims, and that it is not necessary for the Applicants to demonstrate that large amounts of surfactants interfere with either the polymeric sulfonic acid gelling agent or prevent the gelling process, as suggested by the Examiner. The Applicants are not claiming that large amounts of surfactants interfere with the gelling agent or the gelling process. Neither Wheeler nor Clariant recognizes that an aqueous composition comprising biliquid foam and electrolytes can be stabilized at acidic pH with less than 1% surfactant in the total composition, the stability of the gel being unaffected by acids when polysulfonic acid gellant is employed. The superiority of the polymeric sulfonic acid gellant in the biliquid-containing dispersions of the present invention is unexpected and not suggested by the references cited. The unexpected results unequivocally rebut any *prima facie* case of obviousness that may be found in combining

the Wheeler and Clariant references. ((*In re Soni*, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995). When an applicant demonstrates substantially improved results, as Soni did here, and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary.)) Therefore, withdrawal of the rejection of the claims under 35 USC §103(a) is respectfully requested.

CONCLUSION

The present claims are believed to be in condition for allowance, and prompt issuance of a Notice of Allowance is respectfully solicited. The Examiner is encouraged to contact the undersigned by telephone if it is believed that discussion will resolve any outstanding issues.

Respectfully submitted,

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